UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA ex rel., and
STATE OF NEW YORK ex rel.,
MICHAEL I. LEVINE, M.D.,

Docket No.: 12-cv-05103-LGS

Plaintiff-Relator,

v.

ROBERT MATALON, MD, JOSEPH SHAMS, MD,
DANIEL MATALON, MD, ALBERT MATALON, M.D,
VASCULAR ACCESS CENTERS (and each of its
subsidiary and/or related Corporations),
JAMES McGUCKIN, MD (and any and all clinics owned,
run, managed or operated by him),
PHILADELPHIA VASCULAR INSTITUTE,

Defendants.

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DEFENDANT DR. JOSEPH SHAMS, M.D.'S MEMORANDUM OF LAW
IN SUPPORT OF HIS MOTION TO DISMISS THE AMENDED COMPLAINT

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Defendant Dr. Joseph Shams, M.D. ("Shams"), by his counsel Cohen Tauber Spievack & Wagner P.C., respectfully submits this memorandum of law in support of his motion to dismiss the Amended Complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

This is the paradigmatic case of guilt by association. Extrapolating from (i) a single telephone call concerning a single patient and (ii) Plaintiff-Relator Michael Levine's ("Levine" or "Relator") knowledge of different physicians' (but not Shams's) alleged fraudulent actions at different medical practices, involving different patients, in different *qui tam* actions, Levine concocts a baseless theory that Shams—a prominent, well-respected interventionist radiologist who performs procedures to treat access sites for dialysis patients—engaged in a scheme to schedule patients for medically unnecessary follow-up appointments, reimbursed by Medicare, in order to defraud the United States Government.

Levine's efforts to assert claims under both the federal False Claims Act, 31 U.S.C. § 3729 ("FCA"), and the New York False Claims Act, Fin. Law § 189 ("NYFCA") fail completely. *First*, Levine's entire theory of fraud rests upon third-hand information and publicly disclosed fraudulent acts in other *qui tam* cases against other defendants (on which the Amended Complaint explicitly relies to fill the numerous gaps in the pleading). Thus, Levine is not an "original source" under the FCA. This Court, therefore, lacks subject matter jurisdiction, and the Amended Complaint must be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).

Second, the Amended Complaint fails to allege the particularized facts required under Fed. R. Civ. P. 9(b) for any FCA violation. Levine fails to (i) allege that any patient even attended a

supposedly unnecessary follow-up appointment, or (ii) tie a single false claim submitted to the government to any purportedly fraudulent conduct by Shams.

Third, the Amended Complaint fails to adequately allege particularized facts giving rise to a strong inference of fraudulent intent by Shams, as there is no non-conclusory allegation that Shams had motive to commit fraud or that he acted recklessly.

Finally, the Amended Complaint should be dismissed because the claims are time-barred. The only potentially alleged fraudulent conduct occurred in, at the latest, 2009. And, even if the relation-back doctrine under Fed. R. Civ. P. 15 were available to a relator in a *qui tam* action (it is not), the Amended Complaint relies on a totally new set of operative facts and, accordingly, cannot relate back, for statute of limitations purposes, to the initial pleading filed in 2012.

For these reasons, as set forth more fully below, the Amended Complaint should be dismissed in its entirety.

RELEVANT FACTUAL ALLEGATIONS[1]

The Amended Complaint purportedly concerns the unnecessary provision of "'vascular access services' and percutaneous interventions upon ESRD [End-Stage Renal Disease] patients and their arteriovenous vascular accesses." (¶ 2)

The Amended Complaint alleges that ESRD "occurs when the kidneys can no longer function at a level necessary for daily life and usually results when chronic kidney disease has progressed to a point where a patient's kidney function is less than ten percent of normal kidney function." (¶ 31) ESRD patients require hemodialysis to remain alive. (¶ 33) Medicare and Medicaid provide reimbursement for hemodialysis care to ESRD patients. (*See, e.g.*, ¶¶ 47-54)

[1] The relevant procedural history is set forth in the attached Declaration of Stephen Wagner, dated October 24, 2019 ("Wagner Decl."). Citations to "¶ _" refer to paragraphs in the Amended Complaint, annexed as Exhibit 3 to the Wagner Decl.

To perform hemodialysis, there must be access to the patient's circulatory system, known as "vascular access." (¶ 40) The two preferred methods for gaining access to a patient's arteries and veins are (i) grafts and (ii) fistulas. (¶ 42) The Amended Complaint acknowledges the hemodialysis patients routinely suffer from complications related to their access sites, including, "the formation of narrowings or stenoses within the fistula or graft vessel itself and/or the vein(s) drawing the artery(s) feeding the access." (¶ 43) Left untreated, such "narrowings within a patient's vascular access system will often progress, ultimately leading to critical access failure…and/or significant clinical complications such as arm swelling or prolonged bleeding following dialysis needle removal." (¶ 44)

When there is a clinically significant obstruction in the patient's vascular access system, the dialysis provider and the patient's primary or treating nephrologist will refer the patient to a vascular access specialist (such as an interventionist radiologist) to perform a fistulagram (*i.e.*, a radiographic imaging of the access system)). (¶ 4) If necessary, the vascular access specialist will perform a percutaneous or endovascular procedure, such as an angioplasty, to repair the patient's vascular access. (¶ 4) "An angioplasty is a procedure for clearing a vascular blockage or narrowing (stenosis) by inserting a catheter with a balloon attached into the patient's blood stream so as to physically expand the width of the narrowed vessel." (¶ 5 n.2) Levine alleges that access centers have no role in monitoring a patient's access or determining whether additional corrective procedures are necessary. (¶ 68)

Shams is board certified in interventional radiology and allegedly had admitting privileges at Beth Israel, an acute care hospital in New York City. (¶¶ 25-26)

Dr. Robert Matalon ("R. Matalon") is a nephrologist and associate professor of clinical medicine at NYU Langone Medical Center. (¶ 22) Dr. Albert Matalon ("A. Matalon") and Dr.

Daniel Matalon ("D. Matalon," together with R. Matalon and A. Matalon, the "Matalon Defendants") are R. Matalon's sons and are both internists and nephrologists. (¶¶ 23-24)

Levine claims to be an "Internal Medicine physician" who is board certified in internal medicine and nephrology. (¶ 10) Levine alleges that he is "trained in the diagnosis and management of kidney disease and/or kidney disorders." (¶ 10) While he claims to have "trained as an interventional nephrologist" and has performed some unspecified number of the "very procedures at issue in this matter," Levine does not allege that he has ever routinely practiced as an interventional nephrologist. (¶ 10)

Levine was employed by McGuckin from the end of March 2009 through July 2009. (¶ 16) Levine allegedly worked with the Matalon Defendants at some unspecified time, and alleges that the Matalon Defendants referred patients to Shams and/or Beth Israel. (¶¶ 113, 122) Levine does not allege that he ever worked with, or for, Shams or Beth Israel. Aside from a single telephone call (described below), Levine does not allege any interaction with Shams whatsoever.

Levine alleges that Shams and other unnamed Beth Israel radiologists engaged in "self-referrals," whereby Levine's patients "were to return for follow-up appointments for access evaluations even though neither Dr. Levine, nor any of the other healthcare professionals in the dialysis units, initiated the referrals."[2] (¶ 85) Levine contends that *only* a nephrologist may initiate follow-up visits to the interventional radiologists who perform angioplasties, fistulagrams, and other procedures after an initial referral from a nephrologist (despite the fact that the interventional radiologist is the specialist who actually performed the procedure requiring a follow-up appointment).

[2] At various points in the pleading, Levine makes conclusory allegations that such "self-referrals," as performed by McGuckin and Shams, included the performance of medically unnecessary procedures in addition to follow-up office visits. (*See, e.g.*, ¶ 5) Yet, as discussed below, the Amended Complaint does not include any non-conclusory factual allegation that Shams ever performed unnecessary procedure as part of the alleged "self-referrals."

Levine alleges that, at some point in the summer of 2009, a patient named "RG" was referred to Beth Israel for access declotting. (¶ 86) RG allegedly had an angioplasty at Beth Israel, but there is no allegation that Shams performed the procedure or that RG was even Shams's patient. (¶ 86) Levine claims that when he saw RG at some unspecified time, the procedure appeared successful, and he saw no reason for a repeat fistulagram. (¶ 86) Levine alleges that RG was scheduled for a follow-up visit to Beth Israel (without any allegation that *Shams* scheduled or recommended this appointment), but because Levine recommended against it, she did not return for another appointment at Beth Israel. (¶¶ 86, 87)

Levine alleges that, on some unspecified date, Levine called Shams to "see if there was some particular reason the patient needed to be seen so soon after the successful declotting."[3] (¶ 87) Shams purportedly said that it was "their [*i.e.*, Beth Israel's] routine practice to schedule patients for a two week follow-up following angioplasty associated with a percutaneous thrombectomy, and that 'everyone did it' including American Access Care." (¶ 87)[4] Shams also allegedly noted there was a high incidence of clinically significant restenosis post-declotting which, in Levine's opinion, was "contrary to the published medical literature." (¶ 88)

Shams allegedly said that if Levine did not believe a follow-up visit was necessary, RG did not need to return. (¶ 88) While the Amended Complaint posits that this is indicative that Shams and Beth Israel were scheduling medically unnecessary follow-up visits (¶ 88), the Amended Complaint ignores the alternative reason that emerges from the factual allegations: Shams agreed that RG did not have to return to Beth Israel for a follow-up appointment because (i) another physician, Levine, determined the procedure a success, and (ii) Levine told Shams to that RG did

[3] Levine's initial pleading contained no reference to this call. It also does not mention patient RG whatsoever.

[4] Importantly, the only purported direct quote is "everyone does it." The clause "including American Access Care" is therefore clearly not a direct quote.

not have to return for a follow-up visit. (*See* ¶ 88) As such, Levine makes a speculative and illogical leap from Shams accepting Levine's medical opinion to concluding that Shams was requiring patients to attend follow-up appointments without any medical basis. (*See* ¶¶ 88-91)[5]

Levine alleges that in June 2011 his patient "JO" was referred to Beth Israel for a declotting procedure, which was performed successfully. (¶ 92) JO allegedly was scheduled for a two-week follow-up visit, but Levine recommended that JO not return. (¶ 92) Levine does not allege that JO was Shams's patient, that Shams performed any procedure on JO, or that Shams directed JO to return for a follow-up visit. (*See* ¶ 92) Levine does not allege that he ever had any discussion with Shams (or anyone else at Beth Israel) concerning JO. Levine does not allege any facts concerning Shams interacting with, or having any involvement in the treatment of, JO.

Levine also alleges that his patient "MH" had a successful access procedure in February 2011, but had unnecessary follow-up visits thereafter because some unnamed persons at Beth Israel told MH to do so. (¶¶ 93-94) Levine claims that Dr. Steven Haveson was the referring surgeon but that Dr. Haveson was not treating MH at the time MH was referred to Beth Israel.[6] As with JO, Levine does not allege that MH was Shams's patient, that Shams had any role in MH's care, or that Shams referred MH for any follow-up appointments or procedures.

Given the paucity of factual allegations against Shams, Levine attempts, unsuccessfully, to bridge this wide gap by including pages of irrelevant allegations against the original focal point of this action—McGuckin—and a totally unrelated *qui tam* action against American Access Care. The Amended Complaint conspicuously includes references to McGuckin and American Access

[5] The Amended Complaint repeatedly states that RG was scheduled for a "follow-up visit" only, but at one point refers to this as a "follow-up fistulagram." (¶ 87) However, in Levine's purported telephone call, Shams is only alleged to have discussed Beth Israel's purported practice of two-week follow-up *visits* following angioplasties (and not any policy of follow-up *procedures*, such as a fistulagram). (¶ 87)

[6] The Amended Complaint is bereft of any details concerning Dr. Haveson or his hospital/facility affiliation.

Care not because they are in any way relevant, but to tar Shams by association and to bolster the sparse factual allegations concerning Shams's medical practice.

In contrast to the general and non-specific predicate for the allegations against Shams, the Amended Complaint includes detailed and specific allegations about McGuckin's improper practices.[7] Levine allegedly worked for McGuckin between March 2009 and July 2009. (¶ 16) Based on his first-hand knowledge obtained by his employment, Levine alleges that McGuckin, among other things:

- personally instructed Levine that each VAC clinic patient should be "squirted with dye," which meant that they should undergo a fistulagram regardless of whether it was clinically necessary (¶ 75);
- personally instructed Levine to "bang 'em all," which meant that "any and all stenoses were to be angioplastied, and possibly also stented, regardless of how well the access was actually functioning" (¶ 76);
- required that Levine order patients to return for follow-up angioplasties to "secure" newly placed stents, which was medically unnecessary (¶ 77);
- ordered nursing staff to violate Centers for Medicare and Medicaid Services ("CMS") rules and standards for billing practices (¶ 78); and
- had implicit standing orders to perform unnecessary fistulagrams (¶ 79).

Levine alleges that he McGuckin terminated him for his refusal to follow those practices. (¶ 82)

Despite the fact that he does not allege any connection between Shams and McGuckin—Shams is not alleged to have ever worked for or with McGuckin at all—Levine claims that his experience working for McGuckin "informed [his] understanding of what Dr. Shams meant when he stated to Dr. Levine in relation to the case of Dr. Levine's patient RG . . . that 'everyone does it.'" (¶ 74)

[7] Amended Complaint paragraphs 71-83 provide merely a summary of McGuckin and the VAC Defendants' wrongful actions, which are set forth in more detail in the initial pleading and the DOJ's Notice of Intervention. (Wagner Decl. Exs. 1 and 2)

Levine alleges that in June 2015, the DOJ settled a *qui tam* suit against American Access Care Miami LLC, which allegedly engaged in the "same unnecessary and illegal practices as described herein (brought by a different relator)." (¶ 89) Levine recounts a conversation with Dr. Greg Miller at American Access Care in October 2010 (more than a year after his alleged call with Shams) concerning the care for patient KF, whom American Access Care scheduled for a medically unnecessary follow-up appointment two-weeks after a de-clotting procedure. (¶ 90)

Levine alleges that Shams's statement that "'everyone does it' including American Access Care [which, as stated above, is not a direct quote] bolstered Dr. Levine's conclusion" about Shams (¶ 91), despite the fact that Levine's alleged telephone call with Shams occurred at some unspecified date in 2009—more than a year before Levine's conversation with Dr. Miller and six years before the DOJ settled the American Access Care *qui tam* action.[8]

Despite the fact that the Matalon Defendants allegedly referred patients to Shams routinely, Levine does not identify a single Shams patient that actually had a medically unnecessary follow-up appointment or procedure at Beth Israel. Consequently, Levine does not—because he cannot—specify any allegedly improper claims that were submitted to Medicare, let alone that any such claim was actually reimbursed by the government.[9] Instead, the Amended Complaint identifies CMS data for the years 2012 through 2017[10] showing amounts that purportedly reflect Medicare and Medicaid billings and payments for office visits and procedures performed by Shams:

[8] That Shams's alleged passing reference to American Access Care demonstrates fraud is belied by the fact that Levine *voluntarily dismissed his claims against American Access Care*. (ECF Dkt. No. 119)

[9] At best, Levine alleges that MH had follow-up visits and/or procedures at Beth Israel, but does not allege that Shams had anything to do with MH's treatment, or that MH was Shams's patient. In any event, there is no allegation that any improper bills were submitted to Medicare or Medicaid relating to MH.

[10] The Amended Complaint does not indicate why the CMS data was provided for this particular date range, which covers a time period years after Levine's purported conversation with Shams about RG.

Year	Billings submitted	Amount allowed by Medicare	Amount paid
2012	$4,806,017	$374,755	$298,926
2013	$5,220,723	$351,605	$276,117
2014	$4,342,954	$271,979	$212,838
2015	$9,490,786	$2,710,386	$2,124,713
2016	$14,242,155	$4,050,407	$3,175,518
2017	$12,495,154	$4,070,710	$3,188,749

Levine alleges that "[t]he fact that Dr. Shams submitted billings for these procedures to Medicare and Medicaid is confirmed by data maintained by CMS" (¶ 96), but provides no factual allegations supporting his suggestion either that *Shams* personally submitted such billings (rather than the hospital for which he worked) or had any involvement in how *Beth Israel* billed for office visits or procedures.[11]

The Amended Complaint notes that Shams's Medicare billings nearly doubled, and the amounts Medicare paid rose significantly, in 2015, and postulates that Shams must have been submitting false claims to Medicare. (*See* ¶¶ 95, 100-103) However, even a cursory review of the billing codes in the CMS data on which Levine relies reveals that, from 2012 to 2014, Shams primarily performed procedures in a hospital facility; beginning in 2015, he performed procedures in an office setting.[12] (*See* Wagner Decl. Exs. 4-7) Medicare reimburses at a different, higher rate

[11] Levine implies that Shams was personally paid the above amounts from Medicare, despite the fact that he alleges that Shams was employed by Beth Israel, which would have been the entity billing Medicare for services provided by its employees. While not pertinent to this motion, the evidence adduced during discovery will show that Shams had no involvement with the submission of bills to Medicare for reimbursement, which was handled by Beth Israel's staff.

[12] Billing codes are assigned to "each procedure, service or product Medicare covers. Each code has its own payment rate. Places of service are categorized with either an 'F' for health-care facilities, such as hospitals, or with an 'O' for offices, such as doctor's practices." (Wagner Decl. Ex. 4-7 at p.3) Though not relevant on this motion to dismiss, Levine is surely aware that Shams left Beth Israel in or around 2015 and began working in a non-hospital facility.

for procedures performed in an office.[13] Levine does not allege that Shams received any monetary benefit tied to the number of Medicare or Medicaid claims submitted.

Levine alleges that the number of procedures Shams performed indicates that there was a lack of medical necessity.[14] (¶ 104) Specifically, Levine asserts that because Shams was ranked within the top 20 physicians in the country for HCPCT Code 35476—for "Balloon dilation of narrowed or blocked vein"[15] (*i.e.*, an angioplasty of a narrowing located in an access vessel)—then he *must* have billed Medicare for unnecessary angioplasties.[16] (¶¶ 104-108)

Levine hides from this Court that, for numerous billing codes, including 99204 and 99214—for "[e]stablished patient office or other outpatient" visits of 25 or 45 minutes, *i.e.*, codes relevant to the allegation that Shams had patients return for medically unnecessary follow-up office visits—Shams ranked near the bottom nationally for many years.[17] For code 99204, Shams was in the bottom 20% nationally in 2012 and 2013 (and was not ranked at all in 2014). (Wagner Decl. Exs. 4 at 5; Ex. 5 at 5; Ex. 6) For code 99214, Shams was in the bottom 20% nationally in 2014, and in the bottom 40% in 2012 and 2013. (Wagner Decl. Ex. 4 at 5; Ex. 5 at 3; Ex. 6 at 3)

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[13] CMS notes that: "Medicare pays differently when services are provided in a facility setting versus a freestanding physician's office (or other non-facility setting). When services are delivered in a facility setting, Medicare makes two payments, one for the physician's professional fee and one for the facility. . . . For services delivered in a non-facility setting, such as a physician's office . . . the [data] represents the complete payment for the service." (Wagner Decl. Ex. 8 at 15)

[14] CMS warns that there are limitations to its data, including that: "The information presented in this file also does not indicate the quality of care provided by individual physicians…. Additionally the data are not risk adjusted and thus do not account for differences in the underlying severity of disease patient populations treated by providers." (Wagner Decl. Ex. 8 at 14) Moreover, "some providers bill under both an individual NPI [National Provider Identifier] and an organizational NPI. In this case, users cannot determine a provider's actual total because there is no way to identify the individual's portion when billed under their organization." (Wagner Decl. Ex. 8 at 15)

[15] Levine's reliance on CMS data for *angioplasties*—and not the medically unnecessary office visits that were the subject of the purported telephone call with RG—is a telling sleight-of-hand.

[16] Levine essentially alleges that Shams must have defrauded the government because he maintains a busy and successful medical practice. By this reasoning, *all* of the physicians who were ranked higher than Shams must have also violated the FCA.

[17] The Amended Complaint states Levine's legal conclusion and/or opinion that these codes are not intended for follow-up visits following interventional procedures. (¶ 110)

Levine also does not inform this Court that, per CMS data, "[i]n some cases, procedures attributed to a specific physician may have been performed by other people under that doctor's supervision." (Wagner Decl. Ex. 4 at 3; Ex. 5 at 3; Ex. 6 at 3; Ex. 7 at 3)

Finally, Levine alleges that, notwithstanding the fact that the Amended Complaint only alleges a single conversation between Levine and Shams, "at least 27% of the angioplasties performed by Shams" between 2012 and 2017 were medically unnecessary." (¶¶ 128-35) Levine arrived at this figure because a medical expert, in a different case, brought by a different relator, involving different physicians operating in different facilities, upon different patients, determined that "medical necessity could not be justified in the medical records for 27% of the percutaneous transluminal angioplasties . . . reviewed." *Souza v. American Access Care of Miami, LLC*, Civ. No. 1:11-cv-22686-JAL (ECF Dkt. No. 53 at 2) Based upon his speculation that 27% of all angioplasties performed were medically unnecessary, Levine calculates damages as $424,930, before trebling. (¶ 135)

Against this backdrop, the Amended Complaint purports to assert two claims for relief under the FCA and NYFCA: (i) knowingly presenting a false or fraudulent claim and (ii) knowingly making, using, or causing to be made or used a false record or statement.

ARGUMENT

I. THE AMENDED COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(B)(1) BECAUSE LEVINE IS NOT AN "ORIGINAL SOURCE"

Under the FCA, a relator cannot maintain an action if the allegations or transactions in the action were "publicly disclosed" prior to the relator filing suit unless the relator is an "original source" of the information. 31 U.S.C. § 3730(e)(4)(A)-(B). Pursuant to the version of the FCA in effect during the relevant time period,[18]

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions … unless the person bringing the action is an original source of the information. . . . "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based…

31 U.S.C. § 3730(e)(4). Consequently, the failure of a relator to adequately allege that she is an original source is a jurisdictional defect, warranting dismissal of the action for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). *See, e.g.*, *Aryai*, 2019 WL 1258938, at *5.

To be an "original source," a relator must have knowledge of the alleged fraud independent of any public disclosure. The "direct and independent knowledge" test is not met if, as here, "a third party is the source of the core information upon which the *qui tam* complaint is based." *United States ex rel. Dhawan v. N.Y. Medical Coll.*, 252 F.3d 118, 121 (2d Cir. 2001); *see also Aryai*, 2019 WL 1258938, at *5.

[18] For purposes of the public disclosure bar, the version of Section 3730(e)(4) in effect at the time of the allegedly fraudulent conduct applies. *U.S. ex rel. Aryai v. Skanska*, 09 CIV. 5456 (LGS), 2019 WL 1258938, at *3 (S.D.N.Y. Mar. 19, 2019) (Schofield, J.) (applying pre-2010 version of Section 3730(e)(4) where the complaint only alleged fraudulent conduct prior to that date). As discussed in greater detail below in Section II.B, the Amended Complaint does not (i) allege any personal basis for Levine's knowledge of Shams's supposedly fraudulent conduct except for a single telephone call at some unspecified time in 2009 concerning patient RG or (ii) purport to set forth any factual basis for fraud aside from Shams's purported telephone discussion about RG, or even that Shams submitted any claim to Medicare relating to RG. (The Amended Complaint does not allege any specified fraudulent conduct against Shams relating to patients JO and MH, neither of whom is alleged to have been Shams's patient.) Consequently, the version of the FCA in effect in 2009 applies. *Aryai*, 2019 WL 1258938, at *3 ("It is well-established that the 2010 amendments to the FCA do not have retroactive effect.").

Levine is not an "original source" under 31 U.S.C. § 3730(e)(4). He does not allege *any* personal knowledge of Shams's medical or billing practices and, aside from a single telephone call, does not allege any direct interaction with Shams. Levine relies exclusively on his knowledge of McGuckin and American Access Care's fraudulent practices to extrapolate a hypothesis that Shams, too, committed fraud. Levine explicitly relies on publicly filed allegations in the American Access Care *qui tam* action and actually cites public filings in that case to plug gaps and express suspicions in the pleading.[19] (¶¶ 87, 89-91, 128 & n.3) Levine also references his conversation with Dr. Greg Miller, the former medical director of American Access Care, and a report about American Access Care patient KF as the basis for his belief that Shams engaged in "unnecessary and illegal practices as a matter of course." (¶¶ 90-91) It is clear that Shams's purported statement that "everyone did it," standing alone, was not the source of Levine's belief that Shams committed fraud; instead, it was Shams's purported reference to *American Access Care* that led to Levine's conclusion that Shams was defrauding Medicare.[20] (¶¶ 89 (describing Shams's purported reference to American Access Care as "telling" because "[i]n June 2015, the [DOJ] settled an FCA qui tam suit against American Access Care Miami LLC alleging that it engaged in the very same unnecessary and illegal practices as described herein (brought by a different relator)."); ¶ 91 ("Thus, Dr. Shams' statement . . . 'everyone did it' including American Access Care bolstered Dr. Levine's conclusion that Dr. Shams engaged in these unnecessary and illegal practices as a matter of course.").)

[19] Levine states that his experience with McGuckin "informed [his] understanding of what Dr. Shams meant…" (¶ 74)

[20] Levine's mere suspicion that Shams' practices violated the FCA is insufficient. *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 353 (4th Cir. 2009) ("Mere suspicion that there must be a false or fraudulent claim lurking around somewhere simply does not carry [relator's] burden of proving that he is entitled to original source status."); *N.Y. Medical Coll.*, 252 F.3d at 121 (denying original source status to relators whose "suspicions of fraud" were based on a publicly available government audit).

Because the allegations about American Access Care and McGuckin—and *not* any direct, first-hand knowledge of Shams's medical practice—form the crux of the fraud allegations in the Amended Complaint, Levine is not an original source and the Court lacks subject matter jurisdiction over this action. *Aryai*, 2019 WL 1258938, at *5-6 ("[T]he only substantive allegation in the TAC specific to Tishman and Plaza is that Relator spoke to executives who confirmed the companies' 'past, current, and future involvement and participation in the gratis pay scheme,' and who 'warned Relator to avoid asking questions about the practice.' This allegation does not demonstrate 'direct and independent knowledge' because the source of Relator's information regarding the fraudulent conduct was a third party."); *U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) (dismissing action where relator had "no significant direct knowledge" of the conduct at issue; a relator's "background knowledge [of] the significance of the information acquired" did not "make its knowledge independent of the publicly disclosed information").[21]

II. THE AMENDED COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(B)(6)

A. Relevant Legal Standards

A complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the facts alleged show "more than a sheer possibility that a defendant has acted unlawfully." *Id*. Sufficient

[21] It would change little if the Court were to determine that any purportedly fraudulent conduct occurred after March 23, 2010. While the 2010 amendment to the FCA removed the jurisdictional bar and modified the definition of "original source," it kept intact a requirement that the relator must have "knowledge that is independent of and materially adds to the public disclosure allegations or transactions." 31 U.S.C. § 3730(e)(4); *see Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 294 (S.D.N.Y. 2013) (following the 2010 amendments to the FCA, the public disclosure bar is no longer jurisdictional). Thus, for the same reasons set forth above, the Amended Complaint should be dismissed pursuant to Rule 12(b)(6) because Levine is not an "original source."

facts must be pleaded to push the claims from merely conceivable to plausible. *Twombly*, 550 U.S. at 570. On a 12(b)(6) motion, the Court need not accept conclusions unsupported by the facts alleged, legal conclusions, bald assertions, or unwarranted inferences. *Iqbal*, 556 U.S. at 678, 680-81; *Twombly*, 550 U.S. at 555-56; *Rolon v. Henneman*, 517 F.3d 140, 149 (2d Cir. 2008).

The Court may consider "documents incorporated into the complaint by reference" and "matters of which a court may take judicial notice" (*Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)), which include "records and reports of administrative bodies." *Jeanty v. Newburgh Beacon Bus Corp.*, No. 17 Civ. 9175, 2018 WL 6047832 at *4 (S.D.N.Y. Nov. 19, 2018). The Court may also consider "documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference [and] documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint." *Id.* at *4 (citation omitted). "[A]llegations contradicted by documents incorporated into the pleadings by reference need not be accepted as true." *Secs. Investor Protection Corp. v. Bernard L. Madoff Inv. Secs. LLC*, 505 B.R. 135, 141 (S.D.N.Y. 2013).

B. The Amended Complaint Should Be Dismissed for Failure to Plead Particularized Facts Showing a Violation of the FCA

"Because the FCA is an anti-fraud statute, *qui tam* complaints filed under the FCA must . . . comply with Rule 9(b) of the Federal Rules of Civil Procedure, which requires a plaintiff to plead fraud claims 'with particularity.'" *U.S. ex rel. Gelbman v. City of New York*, 14-CV-771 (VSB), 2018 WL 4761575, at *4 (S.D.N.Y. Sept. 30, 2018). An FCA complaint "must allege that the defendants (1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *U.S. ex rel. Kolchinsky v. Moody's Corp.*, 238 F. Supp. 3d 550, 556–57 (S.D.N.Y. 2017) (quotation omitted). An FCA complaint must "(1) specify the statements that the plaintiff contends were fraudulent,

(2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Gelbman*, 2018 WL 4761575, at *4.

Significantly, relators are required to plead particularized facts demonstrating both the existence of an underlying fraudulent scheme and the submission of specific false claims to the United States government. *U.S. ex rel. Osmose, Inc. v. Chem. Specialties, Inc.*, 994 F. Supp. 2d 353, 365 (W.D.N.Y. 2014) (an FCA "claim must . . . allege a factual nexus between the improper conduct and the resulting submission of a false claim to the government.") (quotations omitted). The Amended Complaint fails to do either.

1. Levine Fails to Plead Fraudulent Conduct with Particularity

The Amended Complaint fails to allege any actionable fraudulent conduct by Shams. At most, Levine alleges that RG was referred to Beth Israel for an angioplasty and thereafter "was scheduled for a follow-up visit to Beth Israel"—*though not by Dr. Shams*—which Levine did not believe to be medically necessary. (¶¶ 85-88.) However, Levine alleges that, following a discussion he had with Shams, RG *never made a follow-up visit to Beth Israel*. Levine thus fails to detail any specific factual allegations concerning Shams's involvement in any purportedly improper "self-referrals" for which he subsequently submitted or caused to be submitted fraudulent Medicaid or Medicare claims.[22]

Levine attributes a single statement to Shams—it was Beth Israel's practice to schedule follow-up appointments for angioplasty patients and that "'everyone did it'" (¶ 87)—but fails to identify, as required, where and when that statement was made, or explain how or why "everyone did it" was fraudulent in light of the fact he does not allege that Shams submitted a claim relating

[22] While Levine alleges that he and Shams spoke about RG's follow-up appointment, he confusingly also claims that "Shams and the Beth Israel Union Square Center took it upon themselves to schedule RG for a follow-up fistulagram." (¶ 87) But whether it was an office visit or a procedure is a distinction without a difference in this context because RG did *not* attend any follow-up appointment.

to RG.[23] *See, e.g.*, *Aryai*, 2019 WL 1258938, at *9 ("The TAC does not specify which of Skanska's many projects are implicated, nor does it sufficiently allege "where and when" the fraudulent conduct occurred…'") (citation omitted).

Likewise, Levine does not identify when or where any patient actually attended a medically unnecessary follow-up appointment at Shams's behest. Levine does *not* allege that JO and MH were Shams's patients or that Shams had any connection or involvement with their treatment. At best, he alleges that unnamed doctors at Beth Israel made "self-referrals" (*see, e.g.*, ¶¶ 85-86, 92-95), but that is irrelevant to whether *Shams* improperly scheduled medically unnecessary follow-up appointments. Those allegations are plainly insufficient under Rule 9(b) to state a claim against *Shams*. *See, e.g.*, *Aryai*, 2019 WL 1258938, at *8.

2. Levine Does not Allege With the Requisite Particularity any False Claim

The Amended Complaint should be dismissed because it fails to allege that Shams submitted, or caused to be submitted, any false claim to the government relating to patients RG, JO, or MH. "[T]he submission of a false claim is the *sine qua non* of a False Claims Act violation." *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 252–53 (S.D.N.Y. 2014) (quotation omitted).

Levine does not allege that Shams submitted *any* false claim to the government relating to RG, JO, or MH, much less specific factual allegations concerning the dates on which any claim was submitted. *See U.S. ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 132 (E.D.N.Y. 2018) (dismissing FCA claim where the relator failed to allege the dates on which claims were submitted or even an approximate range of dates); *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d

[23] Levine's vague allegation that "about the summer of 2009" RG had a procedure at Beth Israel, with no factual allegations concerning when Levine and Shams spoke on the telephone, is insufficient. *See, e.g.*, *Aryai*, 2019 WL 1258938, at *9.

313, 329 (S.D.N.Y. 2004) ("[T]he defendant's misconduct must be linked to the government's decision to pay.").[24] Nor does Levine explain how Shams could have submitted a false claim for RG or JO, neither of whom actually had a follow-up appointment at Beth Israel.

Instead, the Amended Complaint simply notes that, years after his call with Levine, Shams submitted unrelated claims to Medicare (without identifying any patient for whom such claims were submitted). This effort fails because it does not tie any submission to any fraudulent conduct by Shams. *See, e.g.*, *U.S. ex rel. Tessler v. City of New York*, 712 Fed. Appx. 27, 30 (2d Cir. 2017) (dismissing claim for failure to identify false claims submitted to the government); *U.S. ex rel. Polansky v. Pfizer, Inc.*, 04-CV-0704 (ERK), 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) (dismissing action where relator failed to identify "any false claims").

In any event, as discussed above, Levine merely recites cherry-picked data in a speculative effort to show that, because Shams had a high volume of Medicare claims, he must have submitted false claims to the government.[25] Notwithstanding the fact that the number of claims and procedures performed are not tied to any allegedly fraudulent conduct (and thus this data is entirely irrelevant), Levine's effort is misleading in several respects.[26] *First*, any rise in the amount of Medicare billings is clearly attributable to the fact that beginning in 2015, the procedures were performed in an office, rather than a hospital.[27] (*Compare* Wagner Decl. Ex. 4 at 2 (billing codes

[24] There are likewise no allegations that anyone at Beth Israel submitted false claims relating to these patients.

[25] Bereft of any allegations of actual false claims submitted to Medicare, it is entirely speculative to claim that, because Shams has a busy medical practice, then he *must* have violated the FCA. If the Court were to accept Levine's allegations as viable, then practically every physician with a successful practice performing the same or related procedures could be the subject of a *qui tam* action.

[26] The Court can consider the CMS data, and CMS' commentary thereto (Wagner Decl. Exs. 4-8) because (i) the Amended Complaint incorporates such data by reference, (ii) the CMS data is "integral" to the Amended Complaint, (iii) Levine clearly relied on this CMS data in drafting the Amended Complaint, and (iv) the Court can take judicial notice of records and reports of CMS, a federal administrative body.

[27] By way of example, for billing code 35476 ("Balloon dilation of narrowed or blocked vein"), the average Medicare reimbursement in 2012 was $223.94 per procedure, whereas the average Medicare reimbursement for that same

end in the suffix "F," for "health-care facilities, such as hospitals") *with* Ex. 7 at 2 (billing codes end in the suffix "O," for "offices, such as doctor's practices").)

Second, Levine's reliance on Shams's national rankings for angioplasties is a total red herring because the fraudulent conduct relating to RG is purportedly unnecessary office visits, not angioplasties. Shams consistently ranked near the bottom nationally for certain billing codes relating to office visits. (Wagner Decl. Exs 4 at 5; Ex. 5 at 3, 5; Ex. 6 at 3)

Third, CMS' data does not paint a full picture of the number of procedures performed by any given physician, as "[i]n some case, procedures attributed to a specific physician may have been performed by other people under that doctor's supervision." (Wagner Decl. Ex. 4 at 3)

a. Relator Cannot Rely on *Chorches* to Save his Claims

The Second Circuit's decision in *U.S. ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 82 (2d Cir. 2017) cannot save Levine's claims from dismissal. In *Chorches*, the Second Circuit held that where a relator has made sufficiently strong factual allegations of fraud, she need not have actual knowledge that claims relating thereto were actually submitted to the government. *Id.* at 82-83; *see Tessler*, 712 Fed. Appx. at 30 (*Chorches* held that "a relator who has personal knowledge that records are falsified need not necessarily have personal knowledge that those records were actually submitted where the factual allegations made it highly plausible that the employer submitted falsified records"). If the relator makes such "specific factual allegations," and the relevant bills or invoices submitted to the government are uniquely in the hands of the defendant, the relator may allege upon information and belief that the claims were actually submitted for reimbursement. *Chorches*, 865 F.3d at 83.

procedure in 2015, performed in an office facility, was $1,047.01 per procedure. (*Compare* Wagner Decl. Ex. 4 at 2 *with* Wagner Decl. Ex. 7 at 2)

Here, for the reasons detailed above and in the following section, Levine fails to "adduce specific facts supporting a strong inference of fraud." *Id.* at 82 (quotations omitted). In the case of RG—the sole patient for which Levine alleges personal knowledge of any allegedly fraudulent act committed by Shams—RG did *not* return for a follow-up appointment and so there are no facts supporting any inference that Shams (or Beth Israel) submitted false Medicare claims relating to RG. At best, Levine relies exclusively on speculation and the hypothesis that, because McGuckin and American Access Care were engaged in fraud, Shams must also have been engaged in fraud. This is impermissible under *Chorches*. *Id.* at 86 ("That standard must not be mistaken for license to base claims of fraud on speculation and conclusory allegations. A relator must make allegations that lead to a strong inference that specific claims were indeed submitted and also plead that the particulars of those claims were peculiarly within the opposing party's knowledge."); *Tessler*, 712 Fed. Appx. at 30 ("Tessler lacked personal knowledge that the City failed to recoup the aid-to-continue overpayments to those recipients, and that the City submitted claims for federal reimbursement for any unrecouped overpayments. The SAC alleges only 'hypotheses' and conclusory allegations."); *U.S. ex rel. Kolchinsky v. Moody's Corp.*, 12CV1399, 2018 WL 1322183, at *2 (S.D.N.Y. Mar. 13, 2018) ("generalized claims [that] do not plausibly connect" alleged fraud to "claims submitted to the Government for payment" do not satisfy *Chorches*).

3. Levine Does Not Allege the Requisite Strong Inference of Fraudulent Intent

The FCA provides that only persons *knowingly* submitting, or causing the submission, of false or fraudulent claims can be held liable. *See, e.g.*, 31 U.S.C. § 3729(a)(1); *U.S. ex rel. Kolchinsky v. Moody's Corp.*, 162 F. Supp. 3d 186, 195 (S.D.N.Y. 2016). Because this requirement is "rigorous" and "strict[ly] enforce[d]," *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (2016), the Second Circuit requires relators to plead a particularized factual basis

giving rise to a strong inference of fraudulent intent. *See, e.g.*, *Tessler*, 712 Fed. Appx. at 29-30. Such fraudulent intent "may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Deutsch v. JPMorgan Chase & Co.*, 18-CV-11655 (VSB), 2019 WL 4805689, at *10 (S.D.N.Y. Sept. 30, 2019) (quotations omitted).

Levine does not assert any factual basis that *Shams* acted with scienter. *See Tessler*, 712 Fed. Appx. at 30 ("legal conclusions" of fraudulent intent should not be credited on a motion to dismiss). *First*, Levine does not allege that Shams had a motive to commit fraud: he does not allege that Shams's compensation from Beth Israel—the only entity alleged to have employed Shams—was in any way tied to the number of patient follow-up appointments, the number of procedures performed, or the amount submitted to Medicare. Similarly, there are no non-conclusory allegations that Shams personally (rather than Beth Israel) was *directly* paid by Medicare for any claims submitted. Unlike McGuckin—the owner of a network of vascular access care facilities—and American Access Care, each of which received money from the government tied directly to the volume of claims submitted, Levine does not allege that Shams had any financial motivation to submit false or fraudulent claims to Medicare.

Second, Levine fails to allege facts constituting strong circumstantial evidence of conscious misbehavior or recklessness. At best, as noted above, Shams allegedly stated that "everyone did it"—referring to follow-up appointments after a vascular access procedure—and noted that he had seen a high incidence of restenosis. (¶¶ 87-88) Taking these allegations as true, the Amended Complaint merely indicates that Shams believed that it was medically necessary to have a follow-up appointment and that other practitioners in the field likewise followed this practice. If Shams

believed that "everyone did it," and he had observed high incidences of restenosis, Shams could not have engaged in *conscious* misbehavior or acted in a recklessness manner. *See In re DRDGOLD Ltd. Sec. Litig.*, 472 F. Supp. 2d 562, 572 (S.D.N.Y. 2007) (dismissing claims where "Plaintiffs have essentially employed a pleading technique that couples a factual statement with a conclusory allegation of fraudulent intent in an attempt to create a strong inference of scienter") (quotations omitted).[28]

Accordingly, Levine does not allege any factual basis for fraudulent intent, much less the factual allegations "constituting strong circumstantial evidence" necessary to survive a motion to dismiss. *See, e.g.*, *Tessler*, 712 Fed. Appx. at 30; *U.S. ex rel. Grupp v. DHL Exp. (USA), Inc.*, 47 F. Supp. 3d 171, 177 (W.D.N.Y. 2014) ("Facts that are merely as consistent with fraudulent intent as they are with its absence are insufficient.").[29]

4. The Allegations in the Amended Complaint are Time-Barred

Even if Levine had properly alleged the elements of an FCA claim against Shams—and he has not—the Amended Complaint should be dismissed as untimely.

Qui tam actions are subject to a six-year statute of limitations, which "begins to run on the date the [allegedly false] claim is made, or if the claim is paid, on the date of payment." *U.S. ex rel. Kreindler & Kreindler*, 985 F.2d at 1157; *Aryai*, 2019 WL 1258938, at *6; 31 U.S.C.A. § 3731(b)(1). The Amended Complaint, originally filed on August 5, 2019, does not allege *any* purportedly false or fraudulent action by Shams after some unspecified point in 2009 (and does

[28] That Shams allegedly accepted Levine's medical opinion, and agreed that RG did not have to return for a follow-up appointment, belies any notion of scienter: if Shams intended to defraud, he would have pushed or insisted on RG attending a follow-up appointment.

[29] For the same reasons outlined above, Levine's NYFCA claims should be dismissed. *See Ping Chen*, 966 F. Supp. 2d at 305 (the NYFCA closely tracks the FCA, and the NYFCA claim was dismissed for the same reasons as the FCA claim); *U.S. ex rel. Qazi v. Bushwick United Hous. Dev. Fund Corp.*, 977 F. Supp. 2d 235, 242 (E.D.N.Y. 2013) (same).

not allege that Shams submitted any false claim related to RG, JO, or MH).[30] (*See* ¶¶ 85-94) Consequently, at the absolute latest, the limitations period expired in 2015.

Levine alleges that the claims against Shams are timely because the "false claims are within the 6-year FCA statute of limitations because the statute of limitations relates back to June 29, 2012, when Dr. Levine initially filed this action." (¶ 134) Levine is incorrect.

The Second Circuit has held that relation back under Fed. R. Civ. P. 15(c)(1)(B) is "simply unavailable" to relators alleging violations of the FCA. *Hayes v. Dept. of Educ. of City of New York*, 20 F. Supp. 3d 438, 449 (S.D.N.Y. 2014) ("Rule 15(c)(1)(B) relation back is simply unavailable in suits brought pursuant to § 3730(b)'s procedural requirements.") (citing *United States v. The Baylor U. Med. Ctr.*, 469 F.3d 263, 268 (2d Cir. 2006)); *U.S. ex rel. Hussain v. CDM Smith, Inc.*, 14-CV-9107 (JPO), 2017 WL 4326523, at *10 (S.D.N.Y. Sept. 27, 2017) (same).[31]

But even if the relation-back doctrine applied, it would not save Levine's claims because it is well-settled that claims that are based on an entirely distinct set of factual allegations will *not* relate back to the initial pleading. *See, e.g.*, *Naughright v. Robbins*, 10 CIV. 8451, 2014 WL 5315007, at *6 (S.D.N.Y. Oct. 17, 2014) (new claims did not relate back because the "conduct giving rise" to such claims "was not mentioned in the FAC or the initial complaint"); *Moritz v. Town of Warwick*, 15-CV-5424 (NSR), 2017 WL 4785462, at *4 (S.D.N.Y. Oct. 19, 2017) ("An amendment will not relate back if it sets forth a new set of operational facts; it can only make more specific what has already been alleged.").

[30] While the Amended Complaint alleges that bills were submitted to Medicare after September 2011, there are no factual allegations tying any claim submitted post-2011 to any particular patient who was directed to attend an allegedly unnecessary follow-up visit or undergo an unnecessary procedure.

[31] After *Baylor*, Congress amended the FCA to allow for the *government*'s complaint-in-intervention to relate back to the relator's complaint pursuant to Rule 15(c). This amendment does not apply to the *relator's* pleading. *Hayes*, 20 F. Supp. 3d at 449 (holding that the FCA "amendment expressly extends relation back only to the Government's pleadings, not to those of the relator herself.").

Here, the fraudulent scheme alleged in the Amended Complaint differs radically from that set forth in the initial pleading.[32] Indeed, Shams's name was only referenced in *three* out of a total of 121 paragraphs of the original Complaint. Of those three paragraphs, one paragraph merely alleges that Shams "is board certified in interventional radiology" and lists hospitals with which he is affiliated (Compl. ¶ 17), and one merely mentions Shams in connection with unrelated allegations against R. Matalon (which are no longer alleged in the Amended Complaint). (Compl. ¶ 103) At most, the initial pleading alleged that certain unnamed defendants "farmed out" access surveillance services "to a variety of favored access centers, the most prominent one being the access center run by Joseph Shams, M.D. and his partners at Beth Israel Medical Center." Levine alleged that, thereafter, "*Beth Israel* engaged in the same over-utilization scams as those performed by Dr. McGuckin and discussed in detail above." (Compl. ¶ 97 (emphasis added))

And, the McGuckin "over-utilization scams" that the original Complaint attempts to impute to Beth Israel and Shams concern, in many instances, purportedly wrongful actions that are not raised anywhere in Amended Complaint, including (i) billing for thrombectomies that were not actually performed; (ii) billing for unnecessary angioplasties to remove fibrous sheaths in patient blood vessels; and (iii) using bare metal stents (rather than covered, drug-eluting stents) to ensure that patients needed additional follow-up procedures. (Compl. ¶¶ 89-94)

Because the Amended Complaint concerns an entirely distinct set of factual allegations—indeed, it reads like a completely different action from that filed in 2012—it does not relate back to the initial pleading, and it is time-barred. *See, e.g.*, *Kolchinsky*, 162 F. Supp. 3d at 198–200; *see also U.S. ex rel. Miller v. Bill Harbert Intern. Const., Inc.*, 608 F.3d 871, 882 (D.C. Cir. 2010)

[32] There is no reference to RG, JO, or MH, and there is no discussion of any telephone call between Levine and Shams in the initial Complaint. Nor does it set forth any allegations concerning Shams's billing practices, the volume of claims submitted to Medicare, or the number of procedures performed by Shams, all of which are now, for the first time, alleged in the Amended Complaint.

(allowing "broad and vague allegations to expand the range of permissible amendments after the limitation period has run" in an FCA action would "circumvent the recent teachings of *Iqbal* and *Twombly* by allowing amendments to relate back to allegations that were themselves nothing more than 'naked assertions.'").

CONCLUSION

Based on the foregoing, Shams's motion to dismiss the Amended Complaint should be granted and the action dismissed with prejudice, together with such other and further relief as the Court may deem just and proper.

Dated: New York, New York
October 24, 2019

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